K 123420

510(k) Summary: *syngo*.Breast Care Software

FEB 0 1 2013

Company: Siemens Medical Systems, Inc.
1 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: January 10, 2013

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. General Information:

Importer / Distributor:
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway, E-50
Malvern, PA 19355
Establishment Registration Number: 2240869

Location of Manufacturing Site:
Siemens AG
Medical Solutions
X-Ray Products
Henkestrasse 127
DE-91052 Erlangen
Establishment Registration Number: 3002808157

2. Contact Person:
Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway D-02
Malvern, PA 19355
Phone: (610) 448 -3536 Fax: (610) 448-1787
Email: patricia.d.jones@siemens.com

3. Device Name and Classification

Trade Name:	syngo.Breast Care Software
Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
Submission Type:	510(k) Traditional
Classification Regulation:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ

4. Legally Marketed Predicate Device

Trade Name:	MammoReport^{Plus}
510(k) #:	K042868
Clearance Date:	January 6, 2005
Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.2050
Device Class:	II
Product Code:	LLZ

5. Device Description:

syngo.Breast Care is a software application dedicated to the special needs in breast cancer detection and assessment. *syngo*.Breast Care consists of several software engines, *syngo*.Breast Care Reading, *syngo*.Breast Care CAD Display and *syngo*.Breast Care Tomo, all based on the *syngo*.Breast Care Reading module.

syngo.Breast Care is an optional application for *syngo*.via VA20 (K123375 cleared on November 20, 2012). *Syngo*.via (a Siemens product) offers multi-modality applications and feature sets to support customers in diagnostic imaging for various clinical areas (e.g. general Radiology, Cardiology, Oncology, Neurology, Orthopedics and Women's Health's). Additionally to a multi-client installation, *syngo*.Breast Care may also be configured with *syngo*.via as a single workplace.

6. Indication for Use:

syngo.Breast Care is a dedicated softcopy review environment for both screening and diagnostic Mammography as well as digital breast tomosynthesis. Its user interface and workflow have been optimized to support experienced mammography and tomosynthesis reviewers in both screening and diagnostic reading. Efficiency and reading quality are supported by various specialized features.

syngo.Breast Care provides visualization and image enhancement tools to aid a qualified radiologist in the review of digital mammography images and digital breast tomosynthesis datasets. The radiologist is responsible for making the diagnosis of the images presented.

7. Substantial Equivalence:

The Siemens *syngo*.Breast Care is substantially equivalent to the commercially available Siemens MammoReport^{Plus}. The MammoReport^{Plus} was described in Premarket Notification K042868, cleared 01/06/2005.

8. **Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:**

syngo.Breast Care has a similar intended use as the predicate MammoReport^{Plus}. The *syngo*.Breast Care is a software only solution to run on compatible client server environment together with monitor displays cleared for Mammography as compared to the predicate MammoReport^{Plus} that is a complete hardware and software package.

An optional module enables the display of tomosynthesis datasets providing tomosynthesis specific layouts and tools.

9. **General Safety and Effectiveness Concerns:**

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the *syngo*.Breast Care is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed.

Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed.

10. **Conclusion as to Substantial Equivalence:**

The *syngo*.Breast Care is intended for similar indications for use as the predicate MammoReport^{Plus}. Image display devices with the same or similar specifications will be used to display the mammography images. It is Siemens opinion, that the *syngo*.Breast Care is substantially equivalent to the MammoReport^{Plus}.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 1, 2013

Siemens Medical Solutions USA, Inc.
c/o Ms. Patricia D. Jones
Technical Specialist, Regulatory Submissions
51 Valley Stream Parkway, E-50
MALVERN PA 19355

Re: K123420
Trade/Device Name: *syngo*.Breast Care Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 10, 2013
Received: January 11, 2013

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): _____

Device Name: *syngo*.Breast Care Software

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Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S